Repeat Until It Passes: The QC Habit That Hides the Drift

Nine in ten US labs answer a failed control by running it again. The repeat passes, the record shows a pass, and the drift behind the failure is still there for the inspector to find.

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IN BRIEF

What should a lab do when a QC control fails? Treat it as an event and record four things: what failed, what the lab decided, what it did, and which results reported since the last acceptable control are in question. Repeating the control is one input to that decision. On its own, a passing repeat records nothing about the failure.

Key takeaways

- A repeated control that passes is the expected outcome whether or not the method has drifted, so it proves very little.
- The 2 SD rule rejects about 9% of good runs with two controls, so labs learn to repeat the flag instead of reading it.
- Every rulebook asks the same four things: what failed, what you decided, what you did and which results are in question.
- Results reported between the last acceptable control and the failed one are the inspector's first question.
- A QC event belongs in the record with the batch, so the decision and the corrective action can be found a year later.

On Tuesday at 7:40 the Level II control on the chemistry analyzer comes up 2.3 SD above the mean. The analyst runs it again from the same vial, and the repeat lands at 0.8 SD. The flag clears, the morning batch goes out, and by nine nobody remembers it.

You know that morning. About 89% of US labs handle a failed control the same way, according to Westgard QC's 2025 Great Global QC Survey. More than 46% see a failure every day.

Running the control again doesn't tell you why it failed, and it doesn't record what you decided. Treat a QC failure as an event. Record what failed, what you decided, what you did, and which results since the last acceptable control are in question. A passing repeat answers none of those.

We'll follow Tuesday's batch through that record, whether yours lives on paper or in a laboratory information system.

Why does a repeated control usually pass?

A repeated control usually passes because the arithmetic says it will. CLIA requires two levels a day. With 2 SD limits on both, about 9% of your good runs throw a flag with nothing wrong, and with three levels it's 14%. More than two-thirds of US labs still use 2 SD limits for rejection, or for warning and rejection.

Tuesday's 2.3 SD value could have been one of those false alarms, and the 0.8 SD repeat is exactly what you'd expect if it was. You'd also expect that repeat if the method had shifted a little, because one value on its own can't tell a small shift from noise.

The passing repeat tells you the control is in now, but it doesn't tell you why the first one was out.

Some labs widen their limits to quiet the flags. Sten Westgard warned in 2007 that with wider limits "you don't know what errors you are detecting and what errors you simply are letting out the door."

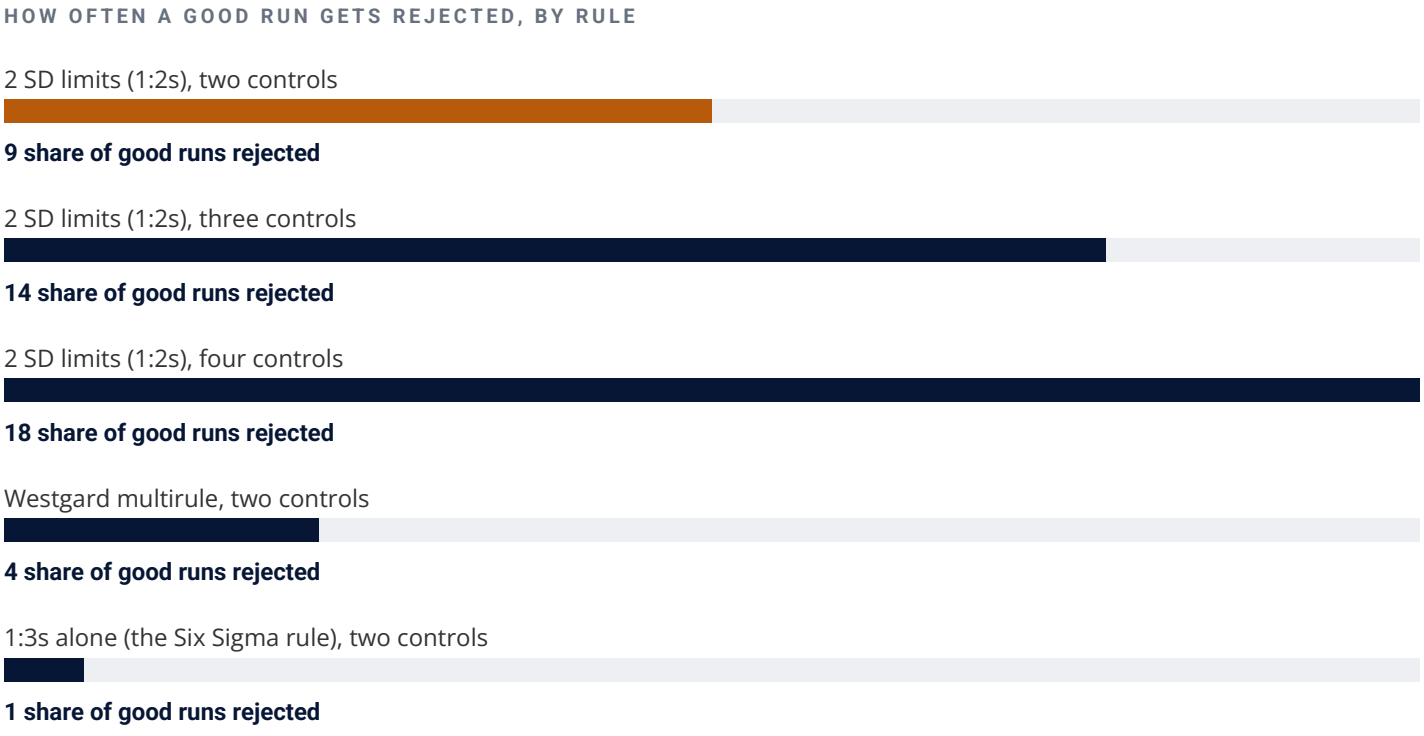
The habit is an old one. In a 1998 CAP Q-Probes study of 505 hospital labs, "More than 95% of the time, participants resolved out-of-control events simply by repeating controls." The 2025 survey says the habit is still with us.

What is the repeat actually hiding?

Repeating the control can hide a drift. The rules that catch drift, 4:1s and 10:x, read the sequence of points. A repeat swaps the one value those rules need for a value that passed.

On Tuesday's chart the 2.3 SD point was the eighth in a row above the mean, and nobody looked past it to the seven before. The 0.8 SD repeat is above the mean too. That makes it the ninth point in a row, so the repeat that cleared the flag was part of the drift. On a multirule chart, one more point above the mean trips 10:x.

The multirule procedure that Westgard, Barry, Hunt and Groth published in 1981 cuts false rejection to about 3% to 4% and still reads the sequence. A Six Sigma method needs only 1:3s with two controls, at about 1%.



Westgard QC; CLP, Sept 2026

The survey shows what happens when the repeat fails too. About 75% of US labs then run a new control, and about 23% repeat that one as well. Over 4% keep repeating "as much as necessary to get 'in'." As Sten

Westgard put it, “this is not the act of a clinical facility, this is the act of a casino.”

What does every rulebook require when a control fails?

Every rulebook asks for the same four things in its own words. CLIA, ISO/IEC 17025, TNI and 21 CFR 211 each want a record of what failed, what you decided, what you did, and which results are in question. Find your row.

REGIME	WHAT FAILED	WHAT YOU DECIDED	WHAT YOU DID	RESULTS IN QUESTION
CLIA	All control procedures documented, 493.1256(g)	Controls acceptable before reporting, 493.1256(f)	Every corrective action documented, 493.1282(b)	Since the last acceptable run, 493.1282(b)(2)
ISO/IEC 17025	Recorded so trends are detectable, 7.7.1	Decision on acceptability, 7.10.1(d)	Halt work, withhold reports, 7.10.1(b)	Impact on previous results, 7.10.1(c)
TNI	Batch out of control, 1.7.3.2.1	Procedure names who assesses, Module 2 4.11.6	Documented in all cases, 1.7.4.1(c)	Samples suspect, 1.7.4.2(a)
21 CFR 211	Deviations recorded and justified, 211.160(a)	Written conclusions, 211.192	Thorough investigation, 211.192	Even if distributed, 211.192

FDA cited 211.192 164 times in fiscal 2025 on Form 483s issued through its electronic system. That clause says a failure “shall be thoroughly investigated, whether or not the batch has already been distributed.”

Under all four rulebooks, Tuesday’s batch has the same gap. It has a flag and a pass, but nobody recorded a decision.

Which results are in question, and who decides?

Every result reported since the last acceptable control on that analyte and instrument is in question, and your procedure has to name who evaluates them. CMS’s surveyor guidance asks, “has the laboratory

evaluated all patient test results since the last acceptable quality control?"

On Tuesday that means more than the morning batch. If the last control that passed ran Monday afternoon, Monday afternoon's results are in question too.

Only a third of US labs retest all patient samples after an out-of-control run. Releasing with a reason is a legitimate answer. What gets you cited is having no record of which answer you gave.

The person who decided has to be on the record. CAP lists "Inadequate records of supervisory oversight" among the root causes of its top deficiencies for 2022.

An inspector can't find a decision that lives in an email thread, which is why corrective actions tracked in email threads count as a traceability mistake. The same question comes up when an instrument fails as found at calibration.

> NOTE
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> A run rejected by a false alarm still needs a recorded decision. CLIA asks for the evaluation and its record, and ISO/IEC 17025 asks for a decision on acceptability. We would rather see "false rejection, no results affected" in the record than a clean chart with a gap.

What does a QC failure record look like?

A QC failure record holds those four things, plus a link to any corrective action. On Tuesday's record, the first field says Level II read 2.3 SD on the 1:2s rule, and that this point and its repeat were the eighth and ninth in a row above the mean.

- **What failed.** The level, value, rule, lot, instrument and time, the last acceptable control, and how many points since sat on one side of the mean
- **What you decided.** Rejected, accepted with a reason, or false rejection, with a reason a stranger can follow a year later and the initials and date of whoever decided
- **What you did.** The troubleshooting and the rerun, in order, and who authorized testing to resume
- **The results in question.** Every result since the last acceptable control, each released, retested, corrected or qualified, and who was notified where a result changed
- **The link.** Any corrective action you opened, and a dated check that it worked

Before your next inspection, pull ten QC failures from the period your inspector will sample. Count the ones that say what you decided, who decided, and what happened to the results since the last acceptable control.

James O. Westgard once quoted a QC action log entry that read, in full, “Repeated, repeated, got lucky!” That entry only shows someone ran the control again, and “repeated, in” doesn’t count either. “False rejection, no results affected,” with initials and a date, does.

For each of the ten, pull up the Levey-Jennings chart and look at the seven points before the failure. If you have a Tuesday of your own, that’s where it shows up.

What LabLynx LIMS does with a failed control

You can keep this record on paper. In the QC logs labs bring us, the decision field is the one most often empty. The list of results in question is the step labs skip, because someone has to pull it by hand for one analyte at 7:40 on a Tuesday.

In clinical chemistry, your middleware may already hold patient results after a QC violation. The decision and the list of results still need a home that an inspector can open a year later. For a lab that records its QC events in its laboratory system, that’s the job of QC in LabLynx LIMS.

> **How LabLynx handles this**
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> In LabLynx LIMS a failed control holds the batch until someone reviews the failure and records a decision. The system builds the list of results since the last acceptable control for that analyte and instrument. The decision, the reason and who made it are on the QC event, and any corrective action links back to it. Send us that count and we'll go through those ten with you, field by field, before anyone talks about software.

Frequently asked questions

How often does a 2 SD control fail when nothing is wrong?

About 1 time in 20 per control. One control lands outside 2 SD about 5% of the time when nothing is wrong with the method. With two controls per run, the 2 SD rule rejects about 9% of good runs. With three it rejects 14%, and with four almost 18%. Repeating the control starts the odds over, so the repeat usually passes.

What are the Westgard rules in QC?

The Westgard rules are a multirule quality control procedure published in 1981 by Westgard, Barry, Hunt and Groth in Clinical Chemistry. Instead of rejecting on any value past 2 SD, they combine rules such as 1:3s, 2:2s, R:4s, 4:1s and 10:x, which cut false rejection to about 3% to 4% while still catching shifts and drift across consecutive controls.

What does CLIA require when QC is out of range?

42 CFR 493.1256(f) says control results must meet the laboratory's acceptability criteria before patient results are reported, and 493.1282(b) requires the laboratory to document all corrective actions taken when controls fail. The same clause requires every patient result in the failed run, and since the last acceptable run, to be evaluated for whether it was adversely affected.

Does ISO/IEC 17025 require QC charts?

ISO/IEC 17025 names control charts as one way to monitor results, where applicable. Clause 7.7.1 requires the laboratory to monitor the validity of its results and to record the data so that trends are detectable. The laboratory chooses the method, and clause 7.7.3 requires action when the monitoring data fall outside its own predefined criteria.

What happens to results reported before a QC failure was found?

They are evaluated, then corrected or qualified if the failure affected them. CLIA 493.1282(b)(2) requires every result since the last acceptable run to be evaluated. ISO/IEC 17025 clause 7.10.1 asks for an impact analysis on previous results, with customer notification and recall where necessary. TNI treats the batch as suspect, to be re-analyzed or reported with qualifying codes.

How many QC failures a day is normal?

Westgard QC's 2025 survey found more than 46% of US labs out of control every day, up from 29% in 2021, and about one lab in three worldwide. The count follows from the rule in use, since 2 SD limits with two controls flag about 9% of good runs. An inspector asks what the lab decided about each one.

Sources and references

1. 42 CFR 493.1256 Standard: Control procedures

   Electronic Code of Federal Regulations

2. ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories, clause 7.7

   International Organization for Standardization

3. 21 CFR 211.160 Laboratory controls, general requirements

   Electronic Code of Federal Regulations

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Read the current version online

https://www.lablynx.com/resources/articles/laboratory-qc-failure-rerun/

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